



*National Institute for
Health Research*

Research Management & Governance (RM&G)

Improving processes for researchers

**Western CLRN Launch Day
Thursday 25 September 2008**

Helen Jones
Lead RM&G Manager
Western Comprehensive Local Research
Network (WCLRN)

Overview

- Streamlining the Regulatory and Governance Environment
 - **Information requirements:** the Integrated Research Application System (IRAS)
 - **NHS R&D permissions:** National Institute for Health Research (NIHR) Co-ordinated System for gaining NHS Permission (CSP)
 - **Issuing of Honorary Research Contracts:** the Research Passport System
 - **Authoritative and consistent provision of advice:** the UKCRC Regulatory and Governance Advice Service (R&G Advice Service)

Integrated Research Application System (IRAS)

- **Streamlining information requirements**
- Recommendation from Department of Health Ad Hoc Advisory Group Report on the NHS REC system- closer administrative arrangements
- *Best Research for Best Health* promised to cut duplication of form filling by researchers
- IRAS collates the information researchers need for permissions and approvals by various regulatory bodies to conduct health and social care research in the UK



Integrated Research Application System (IRAS)

- The system was jointly developed by a group of organisations under the auspices of the UKCRC, led by the National Research Ethics Service
- A single dataset for the application forms for each reviewing body
- The set of questions that need to be answered by a researcher depends on the type of study and the permissions/approvals required
- All the forms cross-populate and are generated from the single dataset

Applications included in IRAS

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines and Devices
- Ministry of Justice (National Offender Management Service)
- NHS / HSC R&D offices
- NRES/ NHS / HSC Research Ethics Committees
- Patient Information Advisory Group (PIAG)



Integrated Research Application System (IRAS)

- IRAS was launched in January 2008 and users were encouraged to give feedback on their experience with the system
- Has been praised by the research community during its consultation-in-use phase, which finished in June
- Uptake has also been high with many applications for research ethics approval being submitted through IRAS
- Further improvements and functionality will continue to be added to IRAS, including the remaining data fields for full European Clinical Trials Database (EudraCT) functionality
- IRAS is the starting point for the Co-ordinated System for gaining NHS Permissions (CSP)
- <https://www.myresearchproject.org.uk/>

Welcome to the Integrated Research Application System (IRAS)

The Integrated Research Application System (IRAS):

- Is a single system for applying for the permissions and approvals for health and social care/ community care research in the UK
- Enables you to enter the information about your project once instead of duplicating information in separate application forms
- Uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required.
- Helps you to meet regulatory and governance requirements
- Retains familiar aspects of the application system provided at www.nresform.org.uk

You can use IRAS to capture the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare products Regulatory Agency (MHRA) - Devices
- Ministry of Justice (National Offender Management Service)
- NHS / HSC research offices
- NRES/ NHS / HSC Research Ethics Committees
- Patient Information Advisory Group (PIAG)

In addition, IRAS provides a simple import/ export mechanism with EudraCT. This covers information needed for applications to Medicines and Healthcare products Regulatory Agency (MHRA) for clinical trials of investigational medicinal products. The information can now be completed in IRAS and exported to the EudraCT system.

Our aim is that the application process should be:

- relevant to your research
- technically easy to use
- supported by accessible guidance and sources of advice

At this time IRAS is available for [consultation-in-use](#) and is not mandatory. Your [feedback](#) is vital as it will be used to further improve IRAS before it becomes compulsory (scheduled for Summer 2008).

Please Login

If you are a first time user of the Integrated Research Application System please read the information on the [help page](#) before you proceed to login.

Login:

(Your full e-mail address)

Password:

Forgotten Password? [Click here](#)

** Passwords are case sensitive.*

*The Integrated Research Application System uses .pdf files to print. You need to have the free Adobe PDF Reader installed on your computer.
[Click here to download the Adobe Reader](#)*



If you have difficulty installing this software please contact your computer administrator.

The Co-ordinated System for gaining NHS Permissions (CSP)

- **Streamlining NHS R&D Permissions**
- National R&D Strategy *Best Research for Best Health* identified unnecessary bureaucracy as a major barrier to clinical research
- UKCRN charged with developing a process to enable streamlined NHS permission
- *“To provide a clinical trial clearing house function, to act as a one-stop shop thereby reducing bureaucracy for studies intended for the NIHR portfolio”* aim in the NIHR Implementation Plan 4.1c, Bureaucracy Busting: NIHR CSP (July 2008)
- UKCRN has developed CSP

NIHR CSP

- CSP is a consistent, standardised process for obtaining NHS permission in England which addresses all quality assurance and statutory research requirements
- For all clinical trials and other well-designed studies (commercial and non-commercial) intended for adoption into the NIHR portfolio
- Coordinated by the CSP Unit based in the UKCRN Coordinating Centre
- Supported by the 25 CLRNs with local input from NHS Trusts to deliver this process

NIHR CSP

- Is supported by CSP ReDA software
- Starting point for CSP is in IRAS
- CSP ReDA will also export data to the UKCRN portfolio database
- Available to studies which are eligible or potentially eligible for entry into UKCRN portfolio
- In time, may be available for other studies
- Will be compatible with systems across the UK



National implementation of CSP- to date

- UKCRN has developed a governance structure to oversee the national implementation of CSP
- Undertaken small scale pilot to evaluate proposed process
- Operating Guidelines for NIHR CSP developed
- CSP ReDA- CLRN Users' Guide developed
- Currently undertaking a large scale pilot with 3 stages
 - **Stage 1:** Testing CSP Study Pathways and CSP ReDA with Lead RM&G Managers in 2 face-to-face sessions- 3/4 July 2008
 - **Stage 2 :** Testing CSP Operating Guidelines and CSP ReDA with NHS Organisations using 9 studies which have been previously approved- commenced 24 September 2008
 - **Stage 3:** Assessing the views of investigators/study co-ordinators in a single session

National implementation of CSP- Sept 08 onwards

- UKCRN plan to implement CSP using a phased approach
- Following the pilot:
 - completion of CSP ReDA before 'go live' date
 - analyse findings from pilot
 - finalisation of the CSP process- Operating Guidelines
 - finalisation of CSP ReDA- CLRN User Guide
- Ongoing focus on CLRN/NHS organisations' readiness



Implementation of CSP in WCLRN

- **Implementation to date:**
- The Lead RM&G Manager has attended:
 - CSP Super User Training (April 2008)
 - CSP Implementation Planning Day (May 2008)
- Identified CSP contacts and user accounts for CSP ReDA
- WCLRN ran 3 CSP User Consultation Workshops in May/June 2008 to introduce NIHR CSP to RM&G staff (the CSP process and CSP ReDA)
- Pro forma/implementation plan in place



Implementation of CSP in WCLRN

- **Next steps:**
- Run a series of training courses on CSP Processes and CSP ReDA during October/November inviting all CSP contacts to attend
- Run a series of briefing sessions on CSP during October/November inviting all WCLRN stakeholders to attend
- Prepare a document/work instructions that sets out the operation of CSP in WCLRN
- Develop guidance/a readiness questionnaire for NHS organisations in WCLRN



The Research Passport System

- **Streamlining the issuing of honorary research contracts (HRCs)**
- Provides a streamlined system for researchers who have no contractual arrangements with the NHS and who need an HRC to carry out research in NHS organisations
- Provides a system for researchers to collect evidence of the necessary checks once only to support their applications for HRCs at multiple NHS organisations
- Provides a streamlined system for NHS organisations to issue HRCs
- Minimises the demand for repeat checks to be undertaken on researchers by providing guidance on the circumstances when it is reasonable to rely on assurances offered by those who have already conducted these checks

The Research Passport System

- The *Research in the NHS - Human Resource (HR) Good Practice Resource Pack* describes the Research Passport system- sets out guidance and good practice available at http://www.nihr.ac.uk/systems_research_passports.aspx
- Developed under the umbrella of the UKCRC by the NHS R&D Forum and the 4 UK Health Departments
- Initially introduced in October 2007 at a national stakeholder event
- UKCRC statement of endorsement in April 2008
- The Research Passport System is now being rolled out across the CLRN



The Research Passport System

- UKCRN established a project to support the implementation of the Research Passport System
- Project Steering Group has been established to provide high level leadership- set the action plan, monitor progress, assist with offering solutions
- The project will provide support to CLRNs
- Each CLRN has been asked to submit a Research Passport Implementation plan to UKCRN
- WCLRN will submit an implementation plan by the end of October 2008



UKCRC Regulatory and Governance Advice Service (R&G Advice Service)

- **Authoritative and consistent provision of advice**
- A UK-wide resource for those involved in health research
- Provides a consistent and authoritative advice on a range of regulatory and governance issues, primarily to support local advice providers such as NHS R&D departments or university research managers
- The R&G advice service does this by providing:
 - A route for handling complex queries, such as those involving more than one regulatory issue
 - Online resources such as toolkits and Questions and Answers
 - <http://www.ukcrc-rgadvice.org/Pages/default.aspx>

UKCRC R&G Advice Service

- CLRN RM&G function- to support researchers through the provision of regulatory and governance advice as part of the R&G Advice Service.
- R&G Advice Service supports the continuation of local advice provision to researchers from RM&G staff
- WCLRN will support the implementation of the UKCRC R&G advice service by:
 - Promoting the advice service within WCLRN, predominantly among RM&G staff
 - Inviting the Advice Service Co-ordinating Team to visit the area to run a briefing session
 - Encouraging all RM&G staff in WCLRN to use the R&G service's online resources
 - Monitoring the use of the R&G advice service in WCLRN
 - Setting up a model of peer advice provision among RM&G staff in WCLRN e.g. maintaining a register of RM&G staff with particular RM&G expertise



Contact details:

Email: HelenZ.Jones@uhbristol.nhs.uk

Tel: 0117 342 0025

Thank you!

The Western Comprehensive Local Research Network is part of the National Institute for Health Research and the UK Clinical Research Network